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SASAN, ARADHANA				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/539,021

Applicant(s)

SAKATA ET AL.

Examiner

ARADHANA SASAN

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 7, 11, 14-18 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 11, 14-18 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 10/30/09 are acknowledged.
2. Claims 1-4, 6, 8-10, 12-13, and 19-20 were cancelled. New claims 21-26 were added. Claim 5 was amended.
3. Claims 5, 7, 11, 14-18, and 21-26 are included in the prosecution.

Response to Declaration

4. The declaration filed 12/03/09, by inventor Yukoh Sakata, has been fully considered. The declaration describes the results of the comparative test between the present invention and the cited reference (Butler et al. (US 3,049,433)). The declarant states in the conclusion that calcium chloride forms white film when used with HPC or HPMC as claimed in the present invention, but does not form a white film when used with HEC or CMC as taught by Butler et al.

This is not persuasive because claims do not require formation of a white film. The components that are required for the film forming composition are (1) a calcium containing compound, and (2) a film forming base agent. Butler clearly teaches these two components in a film forming composition. The "white film" discussed by the declarant is not commensurate in scope with the amended claims. In light of Applicant's amendment of claim 5 to remove calcium chloride, new ground(s) of rejection are made to provide the teaching of a coating composition comprising HPC and calcium lactate (the latter is recited in amended claim 5). New claims 21-26 are still drawn to the

calcium chloride and film forming components (including HPC) and these limitations are taught by Butler.

Therefore, the Declaration is not persuasive.

Response to Arguments

Rejection of claims 5, 7, 11 and 14 under 35 USC § 102(b)

5. In light of Applicant's amendment of claim 5 to remove calcium chloride, Applicant's arguments, see Page 5, filed 10/30/09, with respect to the rejection of claims 5, 7, 11 and 14 under 35 U.S.C. 102(b) as being anticipated by Butler (US 3,049,433) have been fully considered and are persuasive. Therefore, the rejection of 04/30/09 is withdrawn. However, upon further consideration, new ground(s) of rejection are made in view of Kawata et al. (US 4,258,179). The new ground(s) of rejection were necessitated by Applicant's amendment.

Rejection of claims 15-18 under 35 USC § 103(a)

6. In light of Applicant's amendment of independent claim 5 to remove calcium chloride, Applicant's arguments, see Page 5, filed 10/30/09, with respect to the rejection of claims 15-18 under U.S.C. 103(a) as being unpatentable over Butler (US 3,049,433) in view of Iwata et al. (WO 01/40182 A2) have been fully considered and are persuasive. Therefore, the rejection of 04/30/09 is withdrawn. However, upon further consideration, new ground(s) of rejection are made in view of Kawata et al. (US 4,258,179). The new ground(s) of rejection were necessitated by Applicant's amendment.

New claims 21-26

7. Applicant added new claims 21-26, which are drawn to a film forming composition comprising calcium chloride and a water soluble cellulose base polymer selected from the group consisting of methylhydroxyethyl cellulose, hydroxypropyl cellulose and hydroxypropylmethyl cellulose. Since Butler teaches calcium chloride and film forming water soluble cellulose ethers such as hydroxypropyl cellulose, new claims 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Butler (US 3,049,433), and new claims 23-26 are rejected under 35 U.S.C. 103(a) as being obvious over Butler (US 3,049,433) in view of Iwata et al. (WO 01/40182 A2) . Since these new grounds of rejection were necessitated by Applicant's amendment, this action is made FINAL.
- 8.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 5, 7, 11 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawata et al. (US 4,258,179).

The claimed invention is a film-forming composition comprising a calcium-containing compound and a film-forming base agent, wherein the calcium-containing compound is a water-soluble calcium salt selected from the group consisting of calcium

lactate and calcium gluconate and the film-forming base agent is a water-soluble cellulose base polymer.

Kawata teaches coating solid medicaments with coating agents having high impact resistance (Abstract), where the coating agent is in a liquid state (Col. 3, line 55). Kawata discloses spray coating with HPC (hydroxypropyl cellulose) at 3-7% by weight and calcium lactate at 3-15% by weight (Col. 4, lines 32-49). Examples 1, 6, 10, 11 and 12 disclose coating compositions comprising HPC and calcium lactate and coated tablets (Col. 1, lines 1-24, Col. 8, lines 56-67, Col. 10, line 36 to Col. 11, line 40).

Regarding instant claim 7, the limitation of the calcium-containing compound that is provided in a light-shielding agent is anticipated by the calcium lactate taught by Butler (Col. 2, lines 50-69). The instant specification discloses that that "a light-shielding agent contains at least one calcium containing compound" (Page 3, lines 2-6).

Therefore, the limitations of claims 5, 7, 11, and 14-17 are anticipated by the teachings of Kawata.

11. Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Butler (US 3,049,433).

Claim 21 is drawn to a film-forming composition comprising calcium chloride and a water-soluble cellulose base polymer selected from the group consisting of methylhydroxyethyl cellulose, hydroxypropyl cellulose and hydroxypropylmethyl cellulose.

Butler teaches film compositions where a stabilizer is incorporated into a cellulose derivative to eliminate or minimize the discoloration of the cellulose derivatives (Col. 1, lines 38-41). The "...cellulose derivative and stabilizer were mixed together ... and films were cast from the mixture and dried" (Col. 1, lines 62-67). Table 1 summarized the examples and includes calcium chloride at 5.0 percent (Col. 2, lines 50-69). All percentages were by weight and "the percent stabilizer is by weight of the cellulose derivative and both are on a dry basis" (Col. 2, lines 1-4). Percent light transmission through each of the films was determined (Col. 2, lines 14-15). Butler teaches that "very small amounts of stabilizer are effective ... the examples show stabilizing with as little as 0.5% and as high as 10% stabilizer" (Col. 5, lines 19-27). "The compositions (i.e., the mixture comprising the cellulose derivative, stabilizer and solvent for the two) are particularly useful where it is desirable to lay down a deposit, coating or film and evaporate the solvent therefrom ..." (Col. 5, lines 32-38). Water soluble cellulose ethers that can be used in the film compositions including hydroxypropyl cellulose and alkyl hydroxyalkyl cellulose ethers are disclosed (Col. 5, lines 42-53). Water soluble stabilizers are also disclosed (Col. 5, lines 47-48).

Regarding instant claim 21, the limitation of a film forming composition comprising calcium chloride and a water-soluble cellulose base polymer is anticipated by the film forming composition (Col. 1, lines 62-67) comprising water soluble stabilizers (Col. 5, lines 47-48) such as calcium chloride (Col. 2, lines 50-69) and water soluble cellulose ethers including hydroxypropyl cellulose and alkyl hydroxyalkyl cellulose ethers (Col. 5, lines 42-53), as taught by Butler.

Regarding instant claim 22, the limitation of the calcium chloride in an amount of 0.1 to 150% by weight, relative to a weight of the film-forming base agent is anticipated by the 5.0 percent of calcium chloride taught by Butler (Col. 2, lines 50-69).

Therefore, the limitations of claims 21 and 22 are anticipated by the teachings of Butler.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawata et al. (US 4,258,179) in view of Iwata et al. (WO 01/40182 A2).

The teaching of Kawata is stated above.

Kawata does not expressly teach a capsule comprising the film-forming composition according to claim 5.

Iwata teaches a solid preparation that may be "tablets, capsules, granules ..." (Page 22, lines 14-17). Iwata teaches polymeric film coating of the tablets where the polymeric ingredient may be "hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethyl-cellulose" (Page 24, lines 5-11). Iwata also teaches that "in order to protect from light or to improve the discriminability, a suitable

coloring agent may be added into a coating agent. Calcium sulfate (a water soluble calcium salt) is disclosed as a coloring agent that may be used (Page 24, lines 19-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a spray coating composition comprising hydroxypropyl cellulose and calcium lactate used for coating tablets, as taught by Kawata, use the coating composition for coating dosage forms such as tablets, granules and capsules, as taught by Iwata, and produce the instant invention.

One of ordinary skill in the art would do this because Kawata teaches that "by coating solid medicaments with the coating agent, solid medicaments having high impact resistance and showing very less aging can be provided advantageously in industry" (Abstract), and Iwata teaches the film coating of commonly used dosage forms such as tablets, granules and capsules (Page 22, lines 14-17). One of ordinary skill in the art would have a reasonable expectation of success in producing a functional tablet/granule/capsule with a film coating comprising hydroxypropyl cellulose and calcium lactate.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 18, the limitation of a capsule comprising the film forming composition would have been obvious over the teaching by Iwata that the solid preparation that may be "tablets, capsules, granules ..." (Page 22, lines 14-17) and polymeric film coating where the polymeric ingredient may be "hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethyl-cellulose" (Page 24, lines 5-11). Regarding the limitation of coating by a spraying method, it would be obvious over the spray coating taught by Kawata (Col. 4, lines 32-49) and over the spraying of hydroxypropylcellulose, as taught by Iwata (Page 42, lines 4-9).

14. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler (US 3,049,433) in view of Iwata et al. (WO 01/40182 A2).

The teaching of Butler is stated above.

Butler does not expressly teach a formulation (tablet, granule or capsule) coated with the film-forming composition.

Iwata teaches a solid preparation that may be "tablets, capsules, granules ..." (Page 22, lines 14-17). Iwata teaches polymeric film coating of the tablets where the polymeric ingredient may be "hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethyl-cellulose" (Page 24, lines 5-11). Iwata also teaches that "in order to protect from light or to improve the discriminability, a suitable coloring agent may be added into a coating agent. Calcium sulfate (a water soluble calcium salt) is disclosed as a coloring agent that may be used (Page 24, lines 19-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a film composition with a water soluble cellulose ether (such as hydroxypropyl cellulose and alkyl hydroxyalkyl cellulose ethers) and a water soluble stabilizer (such as calcium chloride), as taught by Butler, substitute it for the film coating composition that coats dosage forms such as tablets, granules and capsules, as taught by Iwata, and produce the instant invention.

One of ordinary skill in the art would do this because Butler teaches that the film composition is particularly useful where it is desirable to lay down a deposit, coating or film (Col. 5, lines 32-38) and Iwata teaches the film coating of commonly used dosage forms such as tablets, granules and capsules (Page 22, lines 14-17). One of ordinary skill in the art would have a reasonable expectation of success in producing a functional tablet/granule/capsule with a film coating comprising a water-soluble cellulose ether and a water-soluble calcium salt.

Regarding instant claims 23-26, the limitation of a formulation with the film-coating composition would have been obvious over the teaching by Iwata that the solid preparation that may be "tablets, capsules, granules ..." (Page 22, lines 14-17) and polymeric film coating where the polymeric ingredient may be "hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethyl-cellulose" (Page 24, lines 5-11). Regarding the limitation of coating by a spraying method, it would be obvious over the spraying of hydroxypropylcellulose, as taught by Iwata (Page 42, lines 4-9).

Conclusion

15. No claims are allowed.
16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615